



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Andrew R. Marks, et al. Docket No.: 5199-144
Serial No.: 10/809,089 Examiner: to be assigned
Filed: March 25, 2004 Group Art Unit: 1624
Title: **NOVEL ANTI-ARRHYTHMIC AND HEART FAILURE DRUGS
THAT TARGET THE LEAK IN THE RYANODINE RECEPTOR
(RyR2) AND USES THEREOF**

November 23, 2004

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.97(b)

Sir:

In accordance with the duty of disclosure under 37 CFR §1.56, applicant hereby notifies the U. S. Patent and Trademark Office of the following documents, which are listed on the attached PTO/SB/08A and PTO/SB/08B forms. The examiner may deem these documents to be relevant to patentability of the claims of the above-identified application. Copies of the documents are enclosed for the examiner's convenience.


The submission of the listed documents is not intended as an admission that any of the documents constitute prior art against the claims of the present application. Applicants do not waive any right to take any action that would be appropriate to antedate or otherwise remove any listed document as a competent reference against the claims of the present application.

Applicants respectfully request that the listed documents be considered by the examiner and be made of record in the present application and that initialed copies of Forms PTO/SB/08A and PTO/SB/08B be returned in accordance with MPEP §609.

It is understood that no fee is necessary for submission of this Information Disclosure Statement, because it is being filed before the later of three months from the filing date or the mailing of the first Office Action on the merits.

The Commissioner is hereby authorized to charge payment of any fees associated with this application or credit any overpayment to Deposit Account No. 02-4270.

Respectfully submitted,



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PTO/SB/21 (08-03)

Approved for use through 08/30/2003. OMB 0651-0031

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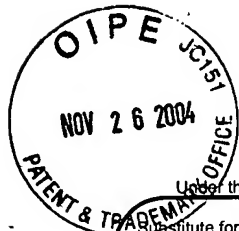
TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/809,089	
	Filing Date	03/25/04	
	First Named Inventor	Andrew R. Marks	
	Art Unit	1624	
	Examiner Name	to be assigned	
Total Number of Pages in This Submission	20	Attorney Docket Number	5199-144

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Technology Center (TC)
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Firm or Individual name	Todd Holmbo, Reg. No. 42,665	
Signature		
Date	11/23/04	

CERTIFICATE OF TRANSMISSION/MAILING			
I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below.			
Typed or printed name	Ping Xiao		
Signature		Date	11/23/04

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Complete if Known	
		Application Number	10/809,089
		Filing Date	03/25/04
		First Named Inventor	Andrew R. Marks
		Art Unit	1624
		Examiner Name	to be assigned
Sheet 1	of 16	Attorney Docket Number	5199-144

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Alvarez et al., Late post-myocardial infarction induces a tetrodotoxin-resistant Na ⁺ current in rat cardiomyocytes.	
		J. Mol. Cell Cardiol., 32: 1169-1179, 2000	
		Antiarrhythmic effects of JTV-519, a novel cardioprotective drug, on atrial fibrillation / flutter in a canine sterile pericarditis model.	
		J. Cardiovasc. Electrophysiol., 14: 880-884, 2003	
		Antos et al., Dilated cardiomyopathy and sudden death resulting from constitutive activation of protein kinase A.	
		Circ. Res., 89: 997-1004, 2001	
		Barbone et al., Comparison of right and left ventricular responses to left ventricular assist device support in patients with severe heart failure:	
		a primary role of mechanical unloading underlying reverse remodeling.	
		Circulation, 104: 670-675, 2001	

Examiner Signature	Date Considered
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

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Sheet 2 of 16	Attorney Docket Number	5199-144	

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		Bennett and Pentecost, The pattern of onset and spontaneous cessation of atrial fibrillation in man.	
		Circulation, 41: 981-988, 1970	
		Bennett et al., Identification and characterization of the murine FK506 binding protein (FKBP) 12.6 gene.	
		Mamm. Genome, 9: 1069-1071, 1998	
		Beuckelmann et al., Intracellular calcium handling in isolated ventricular myocytes from patients with terminal heart failure.	
		Circ., 85: 1046-1055, 1992	
		Brillantes et al., Stabilization of calcium release channel (ryanodine receptor) function by FK506-binding protein.	
		Cell, 77: 513-523, 1994	
		Bristow et al., Decreased catecholamine sensitivity and beta-adrenergic -receptor density in failing human hearts.	
		N. Engl. J. Med., 307: 205-211, 1982	

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Sheet 3 of 16	Attorney Docket Number	5199-144	

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		Burashnikov and Antzelevitch, Reinduction of atrial fibrillation immediately after termination of the arrhythmia is mediated by late phase 3 early afterdepolarization-induced triggered activity.	
		Circulation, 107: 2355-2360, 2003	
		Cameron et al., FKBP12 binds the inositol 1,4,5-trisphosphate receptor at leucine-proline (1400-1401) and anchors calcineurin to this FK506-like domain.	
		J. Biol. Chem., 272: 27582-27588, 1997	
		Chen et al., Mechanism of TGFbeta receptor inhibition by FKBP12.	
		EMBO J., 16: 3866-3876, 1997	
		Chidsey et al., Augmentation of plasma norepinephrine response to exercise in patients with congestive heart failure.	
		N. Engl. J. Med., 267: 650, 1962	

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		Application Number	10/809,089
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		First Named Inventor	Andrew R. Marks
		Art Unit	1624
		Examiner Name	to be assigned
Sheet 4	of 16	Attorney Docket Number	5199-144

NON PATENT LITERATURE DOCUMENTS			
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		Chugh et al., Epidemiology and natural history of atrial fibrillation: clinical implications.	
		J. Am. Coll. Cardiol., 37: 371-378, 2001	
		Cranefield, P.F., Action potentials, afterpotentials, and arrhythmias.	
		Circ. Res., 41: 415-423, 1977	
		Daoud et al., Effect of verapamil and procainamide on atrial fibrillation-induced electrical remodeling in humans.	
		Circulation, 96: 1542-1550, 1997	
		Dun et al., Chronic atrial fibrillation does not further decrease outward currents. It increases them.	
		Am. J. Physiol. Heart Circ. Physiol., 285: H1378-1384, 2003	
		Eichhorn and Bristow, Medical therapy can improve the biological properties of the chronically failing heart. A new era in the treatment of heart failure.	
		Circulation, 94: 2285-2296, 1996	

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Sheet 5	of 16	Attorney Docket Number	5199-144

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		Elvan et al., Pacing-induced chronic atrial fibrillation impairs sinus node function in dogs: electrophysiological remodeling.	
		Circulation, 94: 2953-2960, 1996	
		Fabiato, A., Calcium-induced release of calcium from the cardiac sarcoplasmic reticulum.	
		Am. J. Physiol., 245: C1-C14, 1983	
		Falk, R.H., Atrial fibrillation.	
		N. Engl. J. Med., 344: 1067-1078, 2001	
		Fozzard, H.A., Afterdepolarizations and triggered activity.	
		Basic Res. Cardiol., 87: 105-113, 1992	
		Gaspo et al., Functional mechanisms underlying tachycardia-induced sustained atrial fibrillation in a chronic dog model.	
		Circulation, 96: 4027-4035, 1997	

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NON PATENT LITERATURE DOCUMENTS			
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		Gillo et al., Calcium entry during induced differentiation in murine erythroleukemia cells.	
		Blood, 81: 783-792, 1993	
		Goette et al., Electrical remodeling in atrial fibrillation: time course and mechanisms.	
		Circulation, 94: 2968-2974, 1996	
		Gomez et al., Defective excitation-contraction coupling in experimental cardiac hypertrophy and heart failure.	
		Science, 276: 800-806, 1997	
		Gwathmey et al., Abnormal intracellular calcium handling in myocardium from patients with end-stage heart failure.	
		Circ. Res., 61: 70-76, 1987	
		Hain et al., Phosphorylation modulates the function of the calcium release channel of sarcoplasmic reticulum from cardiac muscle.	
		J. Biol. Chem., 270: 2074-2081, 1995	

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		Hara et al., Steady-state and nonsteady-state action potentials in fibrillating canine atrium: abnormal rate adaptation and its possible mechanisms.	
		Cardiovasc. Res., 42: 455-469, 1999	
		Jayaraman et al., FK506 binding protein associated with the calcium release channel (ryanodine receptor).	
		J. Biol. Chem., 267: 9474-9477, 1992	
		Jayaraman et al., Regulation of the inositol 1,4,5-trisphosphate receptor by tyrosine phosphorylation.	
		Science, 272: 1492-1494, 1996	
		Kaftan et al., Effects of rapamycin on ryanodine receptor / Ca (2+)-release channels from cardiac muscle.	
		Circ. Res., 78: 990-997, 1996	
		Kneller et al., Remodeling of Ca ²⁺ - handling by atrial tachycardia: evidence for a role in loss of rate-adaptation.	
		Cardiovasc. Res., 54: 416-426, 2002	

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		Am. J. Physiol. Heart Circ. Physiol., 14:14, 2002	
		Kumagai et al., Antiarrhythmic effects of JTV-519, a novel cardioprotective drug, on atrial fibrillation / flutter in a canine sterile pericarditis model.	
		J. Cardiovasc. Electrophysiol., 14: 880-884, 2003	
		Laitinen et al., Mutations of the cardiac ryanodine receptor (RyR2) gene in familial polymorphic ventricular tachycardia.	
		Circulation, 103: 485-490, 2001	
		Leenhardt et al., Catecholaminergic polymorphic ventricular tachycardia in children: a 7-year follow-up of 21 patients.	
		Circulation, 91: 1512-1519, 1995	
		Leistad et al., Atrial contractile dysfunction after short-term atrial fibrillation is reduced by verapamil but increased by BAY K8644.	
		Circulation, 93: 1747-1754, 1996	

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
		Application Number	10/809,089
		Filing Date	03/25/04
		First Named Inventor	Andrew R. Marks
		Art Unit	1624
		Examiner Name	to be assigned
Sheet 9	of 16	Attorney Docket Number	5199-144

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
		Levy et al., Long-term trends in the incidence of and survival with heart failure.	
		N. Engl. J. Med., 347: 1397-1402, 2002	
		Marban et al., Mechanisms of arrhythmogenic delayed and early afterdepolarizations in ferret ventricular muscle.	
		J. Clin. Invest., 78: 1185-1192, 1986	
		Marks, A.R., Cellular functions of immunophilins.	
		Physiol. Rev., 76: 631-649, 1996	
		Marks, A.R., Cardiac intracellular calcium release channels: role in heart failure.	
		Circ. Res., 87: 8-11, 2000	
		Marks et al., Progression of heart failure: is protein kinase a hyperphosphorylation of the ryanodine receptor a contributing factor?	
		Circulation, 105: 272-275, 2002	

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		Marx et al., Coupled gating between individual skeletal muscle Ca ²⁺ release channels (ryanodine receptors).	
		Science, 281: 818-821, 1998	
		Marx et al., PKA phosphorylation dissociates FKBP12.6 from the calcium release channel (ryanodine receptor): defective regulation in failing hearts.	
		Cell, 101: 365-376, 2000	
		Mohler et al., Ankyrin-B mutation causes type 4 long-QT cardiac arrhythmia and sudden cardiac death.	
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		Morillo et al., Chronic rapid atrial pacing: structural, functional, and electrophysiological characteristics of a new model of sustained atrial fibrillation.	
		Circulation, 91: 1588-1595, 1995	
		Nabauer et al., Regulation of calcium release is gated by calcium current, not gating charge, in cardiac myocytes.	
		Science, 244: 800-803, 1989	

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		Ono et al., Altered interaction of FKBP12.6 with ryanodine receptor as a cause of abnormal Ca ²⁺ release in heart failure.	
		Cardiovasc. Res., 48: 323-331, 2000	
		Priori et al., Clinical and molecular characterization of patients with catecholaminergic polymorphic ventricular tachycardia.	
		Circulation, 106: 69-74, 2002	
		Priori et al., Mutations in the cardiac ryanodine receptor gene (hRyR2) underlie catecholaminergic polymorphic ventricular tachycardia.	
		Circulation, 103: 196-200, 2001	
		Ramirez et al., Mathematical analysis of canine atrial action potentials: rate, regional factors, and electrical remodeling.	
		Am. J. Physiol. Heart Circ. Physiol., 279: H1767-1785, 2000	
		Reiken et al., Beta-adrenergic receptor blockers restore cardiac calcium release channel (ryanodine receptor) structure and function in heart failure.	
		Circulation, 104: 2843-2848, 2001	

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		Reiken et al., Beta-blockers restore calcium release channel function and improve cardiac muscle performance in human heart failure.	
		Circulation, 107: 2459-2466, 2003	
		Reiken et al., PKA phosphorylation dissociates FKBP12 from the calcium release channel (ryanodine receptor) in skeletal muscle: defective regulation	
		in heart failure.	
		J. Cell Biol., 160: 919-928, 2003	
		Rensma et al., Length of excitation wave and susceptibility to reentrant atrial arrhythmias in normal conscious dogs.	
		Circ. Res., 62: 395-410, 1988	
		Semsarian et al., The L-type calcium channel inhibitor diltiazem prevents cardiomyopathy in a mouse model.	
		J. Clin. Invest., 109: 1013-1020, 2002	

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		Song and Belardinelli, ATP promotes development of afterdepolarizations and triggered activity in cardiac myocytes.	
		Am. J. Physiol., 267: H2005-2011, 1994	
		Sun et al., Cellular mechanisms of atrial contractile dysfunction caused by sustained atrial tachycardia.	
		Circulation, 98: 719-727, 1998	
		Swan et al., Arrhythmic disorder mapped to chromosome 1q42-q43 causes malignant polymorphic ventricular tachycardia in structurally normal hearts.	
		J. Am. Coll. Cardiol., 34: 2035-2042, 1999	
		Tieleman et al., Verapamil reduces tachycardia-induced electrical remodeling of the atrial.	
		Circulation, 95: 1945-1953, 1997	
		Timmermans et al., Immediate reinitiation of atrial fibrillation following internal atrial defibrillation.	
		J. Cardiovasc. Electrophysiol., 9: 122-128, 1998	

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		Valdivia et al., Rapid adaptation of cardiac ryanodine receptors: modulation by Mg ²⁺ and phosphorylation.	
		Science, 267: 1997-2000, 1995	
		Wang et al., Regional and functional factors determining induction and maintenance of atrial fibrillation in dogs.	
		Am. J. Physiol., 271: H148-158, 1996	
		Wehrens et al., FKBP12.6 deficiency and defective calcium release channel (ryanodine receptor) function linked to exercise-induced sudden cardiac death.	
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		Wellens et al., Atrioverter: an implantable device for the treatment of atrial fibrillation.	
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		Wijffels et al., Atrial fibrillation begets atrial fibrillation: a study in awake chronically instrumented goats.	
		Circulation, 92:1954-1968, 1995	

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		Wit and Rosen, Pathophysiologic mechanisms of cardiac arrhythmias.	
		Am. Heart J., 106: 798-811, 1983	
		Yamamoto et al., Abnormal Ca ²⁺ release from cardiac sarcoplasmic reticulum in tachycardia-induced heart failure.	
		Cardiovasc. Res., 44: 146-155, 1999	
		Yano et al., Altered stoichiometry of FKBP12.6 versus ryanodine receptor as a cause of abnormal Ca ²⁺ leak through ryanodine receptor in heart failure.	
		Circulation, 102: 2131-2136, 2000	
		Yano et al., FKBP12.6-mediated stabilization of calcium-release channel (ryanodine receptor) as a novel therapeutic strategy against heart failure.	
		Circulation, 107: 477-484, 2003	
		Yu et al., Tachycardia-induced change of atrial refractory period in humans: rate dependency and effects of antiarrhythmic drugs.	
		Circulation, 97: 2331-2337, 1998	

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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>		Complete if Known	
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		Circ. Res., 81: 512-525, 1997	

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